

§ 3.9

(c) Request for reconsideration by sponsor: If the sponsor disagrees with the designation, it may request the product jurisdiction officer to reconsider the decision by filing, within 15 days of receipt of the letter of designation, a written request for reconsideration not exceeding 5 pages. No new information may be included in a request for reconsideration. The product jurisdiction officer shall review and act on the request in writing within 15 days of its receipt.

§ 3.9 Effect of letter of designation.

(a) The letter of designation constitutes an agency determination that is subject to change only as provided in paragraph (b) of this section.

(b) The product jurisdiction officer may change the designated agency component with the written consent of the sponsor, or without its consent to protect the public health or for other compelling reasons. A sponsor shall be given 30 days written notice of any proposed nonconsensual change in designated agency component. The sponsor may request an additional 30 days to submit written objections, not to exceed 15 pages, to the proposed change, and shall be granted, upon request, a timely meeting with the product jurisdiction officer and appropriate center officials. Within 30 days of receipt of the sponsor's written objections, the product jurisdiction officer shall issue to the sponsor, with copies to appropriate center officials, a written determination setting forth a statement of reasons for the proposed change in designated agency component. A non-consensual change in the designated agency component requires the concurrence of the Principal Associate Commissioner.

[56 FR 58756, Nov. 21, 1991, as amended at 68 FR 37077, June 23, 2003]

§ 3.10 Stay of review time.

Any filing with or review by the product jurisdiction officer stays the review clock or other established time periods for agency action for an application for marketing approval or required investigational notice during the pendency of the review by the product jurisdiction officer.

21 CFR Ch. I (4–1–10 Edition)

Subpart B [Reserved]

PART 5—ORGANIZATION

SUBPARTS A–L [RESERVED]

SUBPART M—ORGANIZATION

Sec.

5.1100 Headquarters.

5.1105 Chief Counsel, Food and Drug Administration.

5.1110 FDA public information offices.

AUTHORITY: 5 U.S.C. 552; 21 U.S.C. 301–397.

SOURCE: 75 FR 16354, Apr. 1, 2010, unless otherwise noted.

Subparts A–L [Reserved]

Subpart M—Organization

§ 5.1100 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER.¹

*Office of the Chief Counsel.*²

*Office of the Administrative Law Judge.*¹

Office of Women's Health.

*Office of Policy, Planning & Budget.*¹

Office of Policy.

Policy Development and Coordination Staff.

Regulations Policy and Management Staff.

Regulations Editorial Section.

*Office of Planning.*¹

Planning Staff.

Evaluation Staff.

Economics Staff.

Risk Communication Staff.

Business Process Planning Staff.

Office of Budget.¹

*Office of Legislation.*³

¹Mailing address: 10903 New Hampshire Ave., Silver Spring, MD 20906.

²The Office of the Chief Counsel (also known as the Food and Drug Division, Office of the General Counsel, Department of Health and Human Services), while administratively within the Office of the Commissioner, is part of the Office of the General Counsel of the Department of Health and Human Services.

³Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

Food and Drug Administration, HHS

\$5.1100

*Office of the Counselor to the Commissioner.*¹

Office of Crisis Management.

Office of Emergency Operations.

*Office of the Chief Of Staff.*¹

Executive Secretariat.

Office of Special Medical Programs.

Office of Good Clinical Practice.

Office of Combination Products.⁴

Office of Orphan Products Development.

Office of Pediatric Therapeutics.³

*Office of International Programs.*³

Office of External Affairs.

*Office of External Relations.*³

Communications Staff.

*Office of Public Affairs.*¹

Web Communications Staff.

*Office of Special Health Issues.*³

Medwatch Staff.

*Office of Foods.*¹

*Office of the Chief Scientist.*¹

Office of Counter-Terrorism and Emerging Threats.³

Office of Critical Path Programs.

Office of Scientific Integrity.

Office of Science and Innovation.

*Office of International Programs.*³

*Office of Administration.*¹

*Office of Equal Employment Opportunity & Diversity Management.*³

Conflict Prevention and Resolution Staff.

Compliance Staff.

Diversity Staff.

*Office of Acquisitions and Grants Services.*⁵

Division of Acquisition Operations.

Division of Acquisition Support and Grants.

Division of Acquisition Programs.

Division of Information Technology.

*Office of Executive Operations.*¹

*Office of Financial Operations.*⁶

*Office of Financial Management.*⁶

Controls, Compliance, and Oversight Staff.

Business Transformation, Administration and Management Staff.

User Fees Staff.

Financial Systems Support Staff.

Division of Accounting.

Division of Budget Execution and Control.

Office of Financial Services.

Division of Payment Services.

Division of Travel Services.

*Office of Information Management.*⁶

Division of Business Partnership and Support.⁶

Division of Chief Information Officer Support.⁶

Division of Systems Management.⁷

Division of Infrastructure Operations.⁸

Division of Technology.⁸

*Office of Management.*³

Ethics and Integrity Staff.

Office of Business Operations and Human Capital Programs.

Office of Management Programs.

Office of Security Operations.

*Office of White Oak Services.*¹

Division of Logistics Services and Facilities Operations.

Division of White Oak Consolidation.

*Office of Shared Services.*⁵

Office of Real Property Services.

Jefferson Laboratories Complex Staff.

Division of Engineering Services.

Environment, Safety And Strategic Initiatives Staff.

Division of Facilities Operations.

Portfolio Development Staff.

Employee Resource & Information Center.

Office of Public Information and Library Services.

Division of Dockets Management.

Division of Freedom of Information.

FDA Biosciences Library.

Public Services Branch.

Technical Services Branch.

⁴Mailing address: 15800 Crabbs Branch Way, Rockville, MD 20855.

⁵Mailing address: 5630 Fishers Lane, Rockville, MD 20857.

⁶Mailing address: 1350 Piccard Dr., Rockville, MD 20850.

⁷Mailing address: 2094 Gaither Rd., Rockville, MD 20850.

⁸Mailing address: 2098 Gaither Rd., Rockville, MD 20850.

§5.1100

FDA History Office.
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH.⁹

Office of the Center Director.

Regulations Policy Staff.

Quality Assurance Staff.

Office of Management.

Regulatory Information Management Staff.

Division of Planning, Evaluation, and Budget.

Division of Veterinary Services.

Division of Program Services.

Division of Scientific Advisors & Consultants.

Building Operations Staff.

Office of Compliance and Biologics Quality.

Division of Case Management.

Division of Inspections and Surveillance.

Division of Manufacturing and Product Quality.

Office of Biostatistics and Epidemiology.

Division of Biostatistics.

Division of Epidemiology.

Office of Information Management.

Division of Information Operations.

Division of Information Development.

Office of Blood Research and Review.

Policy and Publications Staff.

Division of Emerging and Transfusion Transmitted Diseases.

Division of Hematology.

Division of Blood Applications.

Office of Vaccines Research and Review.

Program Operation Staff.

Division of Product Quality.

Division of Bacterial, Parasitic, and Allergenic Products.

Division of Viral Products.

Division of Vaccines and Related Product Applications.

Office of Cellular, Tissue, and Gene Therapies.

Regulatory Management Staff.

Division of Cellular and Gene Therapies.

21 CFR Ch. I (4–1–10 Edition)

Division of Clinical Evaluation and Pharmacology/Toxicology.

Division of Human Tissues.

Office of Communication, Outreach and Development.

Division of Disclosure and Oversight Management.

Division of Manufacturers Assistance and Training.

Division of Communication and Consumer Affairs.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH.¹

Office of the Center Director.

Office of Systems and Management.

Division of Ethics and Management Operations.

Division of Planning, Analysis and Finance.

Division of Information Dissemination.

Division of Information Technology.

Office of Compliance.

Promotion and Advertising Policy Staff.

Division of Bioresearch Monitoring.

Division of Program Operations.

Division of Enforcement A.

Division of Enforcement B.

Office of Device Evaluation.

Program Management Staff.

Program Operations Staff.

Division of Cardiovascular Devices.

Division of Reproductive, Gastro-Renal and Urological Devices.

Division of General, Restorative, and Neurological Devices.

Division of Surgical, Orthopedic and Restorative Devices.

Division of Ophthalmic, and Ear, Nose and Throat Devices.

Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices.

Office of Science and Engineering Laboratories.

Division of Biology.

Management Support Staff.

Standards Management Staff.

Division of Chemistry and Materials Science.

Division of Solid and Fluid Mechanics.

Division of Physics.

⁹Mailing address: 1401 Rockville Pike, Rockville, MD 20852.

Food and Drug Administration, HHS

\$5.1100

Division of Imaging and Applied Mathematics.
Office of Communication, Education and Radiation Programs.
Program Operations Staff.
Regulations Staff.
Staff College.
Division of Device User Programs and Systems Analysis.
Division of Small Manufacturers Assistance.
Division of Mammography Quality and Radiation Programs.
Division of Communication Media.
Office of Surveillance and Biometrics.
Issues Management Staff.
Division of Biostatistics.
Division of Postmarket Surveillance.
Division of Surveillance Systems.
Office of In Vitro Diagnostic Device Evaluation and Safety.
Division of Chemistry and Toxicology Devices.
Division of Immunology and Hematology Devices.
Division of Microbiology Devices.
Division of Radiological Devices.
CENTER FOR DRUG EVALUATION AND RESEARCH.¹⁰
Office of the Center Director.
Controlled Substance Staff.
Office of Regulatory Policy.
Division of Regulatory Policy I.
Division of Regulatory Policy II.
Division of Regulatory Policy III.
Division of Information Disclosure Policy.
Office of Management.
Division of Management and Budget.
Division of Management Services.
Office of Communications.
Division of Information Services.
Division of Public Affairs.
Division of Drug Information.
*Office of Surveillance and Epidemiology.*¹¹

Review and Management Staff.
Business Process Improvement Staff.
Regulatory Policy Staff.
Division of Medication Error Prevention and Analysis.
Division of Pharmacovigilance I.
Division of Pharmacovigilance II.
Division of Drug Risk Evaluation.
Division of Epidemiology.
*Office of Compliance.*¹
Division of Compliance Risk Management and Surveillance.
Division of New Drugs and Labeling Compliance.
Division of Manufacturing and Product Quality.
Division of Scientific Investigations.
*Office of New Drugs.*²
Pediatric and Maternal Health Staff.
Program Management Analysis Staff.
Office of Drug Evaluation I.
Division of Cardioresenal Cardiovascular and Renal Drug Products.
Division of Neurology Products.
Division of Psychiatry Products.
Office of Drug Evaluation II.
Division of Metabolism and Endocrinology Products.
Division of Pulmonary, Allergy and Rheumatology Products.
Division of Anesthesia and Analgesia Products.
Office of Drug Evaluation III.
Division of Gastroenterology Products.
Division of Reproductive and Urologic Products.
Division of Dermatology and Dental Products.
Office of Antimicrobial Products.
Division of Anti-Infective and Ophthalmology Products.
Division of Anti-Viral Products.
Division of Special Pathogen and Transplant Products.
Office of Drug Evaluation IV.
Division of Nonprescription Clinical Evaluation.
Division of Nonprescription Regulation Development.
Division of Medical Imaging Products.
Office of Oncology Drug Products.

¹⁰Mailing address: 10903 New Hampshire Ave., White Oak Bldg. 51, Silver Spring, MD 20993.

¹¹Mailing address: 10903 New Hampshire Ave., White Oak Bldg. 22, Silver Spring, MD 20993.

§5.1100

Division of Drug Oncology Products.
Division of Hematology Products.
Division of Biologic Oncology Products.
*Office of Pharmaceutical Science.*¹
Program Activities Review Staff.
Operations Staff.
Science and Research Staff
New Drug Microbiology Staff.
*Office of Generic Drugs.*¹²
Division of Bioequivalence.
Division of Labeling and Program Support.
Division of Chemistry I.
Division of Chemistry II.
Division of Chemistry III.
*Office of New Drug Quality Assessment.*¹³
Division of New Drug Quality Assessment I.
Division of New Drug Quality Assessment II.
Branch IV.
Branch V.
Branch VI.
Division of New Drug Quality Assessment III.
Branch VII.
Branch VIII.
Branch IX.
*Office of Testing and Research.*²
Laboratory of Clinical Pharmacology.
Division of Applied Pharmacology Research.
Division of Pharmaceutical Analysis.
Division of Product Quality Research.
*Office of Biotechnology Products.*⁴
Division of Monoclonal Antibodies.
Division of Therapeutic Protein.
*Office of Medical Policy.*²
Division of Drug Marketing, Advertising and Communication.
*Office of Executive Programs.*¹
Division of Training and Development.
Division of Executive Operations.
Division of Advisory Committee and Consultant Management.

¹²Mailing address: 7519 Standish Pl., Bldg. MPN4, Rockville, MD 20855.

¹³Mailing address: 10903 New Hampshire Ave., White Oak Bldg. 21, Silver Spring, MD 20993.

21 CFR Ch. I (4–1–10 Edition)

*Office of Translational Sciences.*⁴
Office of Biostatistics.
Division of Biometrics I.
Division of Biometrics II.
Division of Biometrics III.
Division of Biometrics IV.
Division of Biometrics V.
Division of Biometrics VI.
Division of Biometrics VII.
*Office of Clinical Pharmacology.*¹
Division of Clinical Pharmacology I.
Division of Clinical Pharmacology II.
Division of Clinical Pharmacology III.
Division of Clinical Pharmacology IV.
Division of Clinical Pharmacology V.
Division of Pharmacometrics.
Office of Counter-Terrorism and Emergency Coordinator.
Office of Planning and Informatics.
Office of Planning and Analysis.
Planning and Evaluation Staff.
Analysis Staff.
Office of Business Informatics.
Division of Records Management.
Division of Regulatory Review Support.
Division of Business Analysis and Reporting.
Division of Project Development.
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION.¹⁴
Office of the Center Director.
Senior Science Advisor Staff.
Executive Operations Staff.
International Staff.
Office of Management Systems.
Division of Planning and Financial Resources Management.
Division of Program Support Services.
Office of Food Defense, Communication and Emergency Response.
Division of Education and Communication.
Division of Public Health and Biostatistics.
Office of Food Safety.
Retail Food and Cooperative Programs Support Staff.

¹⁴Mailing address: 5100 Paint Branch Pkwy., College Park, MD 20740-3835.

Food and Drug Administration, HHS

§ 5.1100

Division of Seafood Science and Technology.

Division of Food Processing Science and Technology.

Division of Plant and Dairy Food Safety.

Division of Seafood Safety.

Office of Cosmetics and Colors.

Cosmetic Staff.

Division of Color Certification and Technology.

Office of Regulatory Science.

Division of Analytical Chemistry.

Division of Microbiology.

Division of Bioanalytical Chemistry.

Office of Food Additive Safety.

Senior Science and Policy Staff.

Division of Food Contact Notifications.

Division of Biotechnology and GRAS Notice Review.

Office of Compliance.

Division of Enforcement.

Division of Field Programs and Guidance.

Office of Applied Research and Safety Assessment.

Muirkirk Technical Operations Staff.

Division of Molecular Biology.

Division of Virulence Assessment.

Division of Toxicology.

Office of Regulations, Policy and Social Sciences.

Regulations and Special Government Employees Management Staff.

Division of Social Sciences.

Office of Nutrition, Labeling and Dietary Supplements.

Food Labeling and Standards Staff.

Nutrition Programs Staff.

Infant Formula and Medical Foods Staff.

Division of Dietary Supplement Programs.

CENTER FOR TOBACCO PRODUCTS.¹⁵

Office of the Center Director.

Office of Management.

Office of Policy.

Office of Regulations.

Office of Science.

¹⁵ Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.

NATIONAL CENTER FOR TOXICOLOGY RESEARCH.¹⁶

Office of the Center Director.

Office of Management.

Office of Executive Programs and Services.

Office of Scientific Coordination.

Office of Research.

Division of Biochemical Toxicology.

Division of Genetic and Reproductive Toxicology.

Genetic Toxicology Laboratory.

Reproductive Toxicology Laboratory.

Division of Personalized Nutrition and Medicine.

Biometry Branch.

Pharmacogenomics Branch.

Division of Microbiology.

Division of Neurotoxicology.

Division of Veterinary Services.

Division of Systems Toxicology.

Office of Regulatory Compliance and Risk Management.

OFFICE OF REGULATORY AFFAIRS.³

Equal Employment Opportunity Staff.

*Office of Resource Management.*³

Division of Planning, Evaluation, and Management.

Division of Human Resource Development.

Division of Management Operations.

Division of Personnel Operations.

Office of Information Technology.

*Office of Enforcement.*⁵

Division of Compliance Management and Operations.

Division of Compliance Policy.

Division of Compliance Information and Quality Assurance.

*Office of Regional Operations.*³

Division of Federal-State Relations.

Division of Field Science.

Division of Import Operations and Policy.

Division of Field Investigations.

*Office of Criminal Investigations.*¹⁷

¹⁶ Mailing address: 3900 NCTR Rd., Jefferson, AR 72079.

¹⁷ Mailing address: 7500 Standish Pl., Rockville, MD 20855.

§ 5.1105

Mid-Atlantic Area Office.³
Midwest Area Office.¹⁸
Northeast Area Office.¹⁹
Pacific Area Office.²⁰
Southeast Area Office.²¹
Southwest Area Office.²²
CENTER FOR VETERINARY MEDICINE.²³
Office of the Center Director.
*Office of Management.*²⁴
Management Logistics Staff.
Financial Resources Staff.
Human Capital Staff.
Learning Management Staff.
*Office of New Animal Drug Evaluation.*²⁵
Division of Therapeutic Drugs for Non-Food Animals.
Division of Biometrics and Production Drugs.
Division of Therapeutic Drugs for Food Animals.
Division of Human Food Safety.
Division of Manufacturing Technologies.
Division of Scientific Support.
Division of Generic Animal Drugs.
*Office of Surveillance and Compliance.*²⁶
Division of Surveillance.
Division of Animal Feeds.
Division of Compliance.
Division of Epidemiology.
*Office of Research.*²⁷
Administrative Staff
Division of Residue Chemistry.

¹⁸Mailing address: 901 Warrenville Rd., Lisle, IL 60532.

¹⁹Mailing address: 10 Exchange Pl., Jersey City, NJ 07302.

²⁰Mailing address: 201 Avenida Fabricante, San Clemente, CA 92672.

²¹Mailing address: 865 SW 78th Ave., Plantation, FL 33324.

²²Mailing address: 5799 Broadmoor St., Mission, KS 66202.

²³Mailing address: 7519 Standish Pl., Bldg. MPN4, rm. 176, Rockville, MD 20855.

²⁴Mailing address: 7529 Standish Pl., Bldg. MPN5, rm. 3577, Rockville, MD 20855.

²⁵Mailing address: 7520 Standish Pl., Bldg. MPN2, rm. 239, Rockville, MD 20855.

²⁶Mailing Address: 7519 Standish Pl., Bldg. MPN5, rm. 300, Rockville, MD 20855.

²⁷Mailing address: 8401 Muirkirk Rd., Bldg. MOD2, rm. G101, Laurel, MD 20708.

21 CFR Ch. I (4–1–10 Edition)

Division of Animal Research.
Division of Animal and Food Microbiology.

*Office of Minor Use and Minor Species Animal Drug Development.*²⁸

§ 5.1105 Chief Counsel, Food and Drug Administration.

The Office of the Chief Counsel's mailing address is 5600 Fishers Lane, rm. 6–05, Rockville, MD 20857.¹

§ 5.1110 FDA public information offices.

(a) *Division of Dockets Management.* The Division of Dockets Management public room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852, Telephone: 301–827–6860.

(b) *Division of Freedom of Information.* The Freedom of Information public room is located in rm. 6–30, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301–827–6567.

(c) *Press Relations Staff.* Press offices are located in White Oak Bldg. 1, 10903 New Hampshire Ave., Silver Spring, MD 20993, Telephone: 301–827–6242; and at 5100 Paint Branch Pkwy., College Park, MD 20740, Telephone: 301–436–2335.

PART 7—ENFORCEMENT POLICY

Subpart A—General Provisions

Sec.
7.1 Scope.
7.3 Definitions.
7.12 Guaranty.
7.13 Suggested forms of guaranty.

Subpart B [Reserved]

Subpart C—Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities

7.40 Recall policy.
7.41 Health hazard evaluation and recall classification.

²⁸Mailing address: 7500 Standish Pl., Bldg. MPN2, rm. N378, Rockville, MD 20855.

¹The Office of the Chief Counsel (also known as the Food and Drug Division, Office of the General Counsel, Department of Health and Human Services), while administratively within the Office of the Commissioner, is part of the Office of the General Counsel of the Department of Health and Human Services.